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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/873,431
Filing Date: June 05, 2001
Appellant(s): KOLTER ET AL.

James Remenick
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 08/08/07 appealing from the Office action mailed 2/27/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is deficient. 37 CFR 41.37(c)(1)(v) requires the summary of claimed subject matter to include: (1) a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number, and to the drawing, if any, by reference characters and (2) for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters. The brief is deficient because for:
Claim 1, appellants' statement that "no melt is present in the granulation," though described page 5, line 11 of the specification, the "no melt is present in the granulation," is not a limitation of the claimed process.
The summary of the claimed subject matter of claims 17 and 25 in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,837,032	**ORTEGA**	**6-1989**
5,389,380	**NODA et al.**	**2-1995**

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Appeal is moot with respect to claims 1-9, 12, 13, 16 and 27-32, which are directed to process for producing an oral dosage form according to the method/process of claim 1. See interview summary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-23, 25 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega (US 4,837,032).

Ortega discloses compressed tablet comprising theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc (abstract; column 2, lines 56-68,. column 3, lines 57-63., and column 4, lines 3-18). The theophylline granule composition is wet granulated from a mixture heated to 40 °C to 50 °C (example 1), which is dried before combining with the mixture of polyvinylpyrrolidone and polyvinyl acetate and lubricant. Stearic acid is listed as an additive in the instant application (page 8, line 20) and the stearic acid of Ortega meets the limitation of additive recited in instant claim 25. Regarding claim 17, which is drawn to composition, it is noted that how the composition is made carries no patentable weight because product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps; and "[e]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Ortega discloses a process of wet granulating a mixture of theophylline, polyvinylpyrrolidone cellulose acetate phthalate; the dried granulate is

then combined with mixture of polyvinylpyrrolidone, polyvinyl acetate and lubricant, which is a mixture or stearic acid, magnesium stearate and talc (abstract; column 2, lines 56-68; column 3, lines 57-63; and column 4, lines 3-18) at a temperature of 40 °C to 50 °C (example 1). In example I, Ortega uses 9 kg of polyvinyl acetate in particle form to 6 kg of polyvinylpyrrolidone which translates into 60 :40 or 6:4 (9/15 to 6/15). Ortega teaches a sustained release composition comprising theophylline, polyvinyl acetate and polyvinylpyrrolidone, cellulose acetate phthalate and optionally lubricant (abstract). Ortega specifically teaches that water-soluble polymers or gel forming polymers are used in the composition and the water-soluble polymers or gel forming polymers in Ortega are polyvinylpyrrolidone and cellulose derivatives such as hydroxypropylcellulose (column 3, lines 49-53). Ortega is silent on the molecular weight of the polyvinylpyrrolidone. Regarding the molecular weight of the polyvinylpyrrolidone recited in instant claims, it is noted from the silence of Ortega on the molecular weight of the polyvinylpyrrolidone, that polyvinylpyrrolidone of any molecular weight can be used except declared by applicants to be contrary to Ortega's invention. The difference therefore, between Ortega and claim 17 is that Ortega is silent on the molecular weight of the polyvinylpyrrolidone. However, the silence of Ortega on the molecular weight of the polyvinylpyrrolidone indicates that polyvinylpyrrolidone having any molecular can be used. It would have been obvious to one of ordinary skill in the art taken the reference of Ortega at the time the invention was made to use polyvinylpyrrolidone having desired molecular weight which when used with the polyvinyl acetate to formulate theophylline dosage form would yield the expected sustained release theophylline dosage form.

(10) Response to Argument

Appellants' arguments with respect to claims 1-9, 12, 13, 16 and 27-32 is moot in view of the offer made to appellant that claims 1-9, 12, 13, 16 and 27-32 are allowable over the prior art.

Appellants argue:

a) That Ortega does not teach dry granulation such that Ortega fails to teach or suggests all the elements of appellants' claims, fails to provide suggestion or motivation necessary for the person of ordinary skill to modify the prior art tablet. Appellants conclude therefore, that, the process of the prior art cannot be "identical or substantially identical" to appellants' claimed process.

b) That appellants' product is not identical with the tablet of the prior art because Ortega produces the tablet by a process that is different from the appealed process.

In view of the above arguments, appellants take the position that the rejection of claim 17 as being unpatentable over Ortega is in error.

Response:

Claim 17 is properly rejected as being unpatentable over Ortega because Ortega discloses a formulation comprising theophylline, a specific active agent meeting the requirements of claim 17 b) for a broad category of active ingredient, polyvinyl acetate and polyvinylpyrrolidone and stearic acid which meets the requirements of claim 17 c) for broad category of additive. Claims 17 c) and d) are optional components and as such the prior art does not have to teach the optional components of the composition of claim 17.

The patentability of the product/formulation of claim 17 is not limited by the manipulations of the recited steps but by the structure implied by the steps in a product by process claim. Appellant has not provided factual showing indicating that the appealed product

is structurally different from the product of the prior art. Furthermore, Ortega produces the theophylline dosage form by a process of granulation (Example I); further still, for the sake of argument, it is noted that appellants process steps in claim 17 involves mixing 17 a) and b) and granulates the mixture by heating at a temperature of from 40 °C to 130 °C, which is what Ortega does by granulating the mixture of theophylline, polyvinyl acetate and polyvinylpyrrolidone and stearic acid and by heating/drying at a temperature of 40-50 °C with the 40 °C of Ortega touching the lower limit of the claimed temperature. The difference between the appealed product and the product of the prior art is not that the prior art product is a tablet and the appealed product is not as appellants appear to be implying, but rather both the prior art and the appealed products are granular even if Ortega makes a tablet form the granulated product. It is also noted that the further method step taught by Ortega, that is compressing the granulates into tablets (Example I) is accommodated by the language of the claim and by the granulated product itself keeping in mind that it is the granules that are made into the table. Thus, no modification of the tablet of Ortega is required or suggested. The difference between appealed claim 17 and the product of the prior art is in the molecular weight of polyvinylpyrrolidone and appellants have not provided factual evidence that polyvinylpyrrolidone having a molecular weight in the broad range of 20,000 to 1,00,000 in combination with polyvinyl acetate and any active agents provides a uniquely different product from the product of the prior art that comprises the specific active agent of theophylline, polyvinyl acetate, polyvinylpyrrolidone and stearic acid.

Thus, regarding argument a) above, the examiner agrees with the appellant that the process of Ortega is not identical or substantially identical to appellants' claimed process, but claim 17 is not a process claim and as such Ortega does not have to teach the identical or

substantially process to render obvious the product claimed in appealed claim 17. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Appealed claim 17 is directed to a product.

Thus, regarding argument b) above, the examiner agrees with the appellant that the product of Ortega is not identical with the appealed product because Ortega is silent on the molecular weight of polyvinylpyrrolidone but at the same time it would be obvious to use polyvinylpyrrolidone having molecular weight that when combined with the polyvinyl acetate, theophylline and stearic acid would lead to the expected sustained release dosage of theophylline.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

BF M.H.Tubara

Conferees:

Hartley, Michael

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SUPERVISORY PATENT EXAMINER

Sreeni Padmanabhan

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